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Arthur L. Lawyer, Ph.D.

President



May 18, 2012

**DuPont Crop Protection:  
Petition to Delete Chlorsulfuron from TRI List**

Mr. Arnold E. Layne  
Director  
Office of Information Analysis and Access (Mail Code 2841T)  
Office of Environmental Information  
Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

Dear Mr. Layne,

On behalf of DuPont Crop Protection (DuPont), Technology Sciences Group Inc. (TSG) respectfully submits the following petition to delete chlorsulfuron from the Toxics Release Inventory (TRI) list of reportable toxic chemicals (40 CFR §372.65).

**Petitioner (on behalf of DuPont Crop Protection)**

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**Action Requested**

Delete chlorsulfuron from the TRI list of reportable toxic chemicals

**Chemical Identity**

Chemical Name: Chlorsulfuron [2-chloro-N-[[5-methoxy-6-methyl-1,3,5-triazin-2-yl]amino]carbonyl]benzenesulfonamide]

Chemical Abstracts Service Registry Number: 64902-72-3

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### **Summary**

On November 30, 1994, the United States Environmental Protection Agency (USEPA or Agency) published a final rule in the *Federal Register* to add 286 chemicals and chemical categories to the list of toxic chemicals subject to reporting under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (USEPA, 1994b). Chlorsulfuron (2-chloro-N-[[5-methoxy-6-methyl-1,3,5-triazin-2-yl]amino]carbonyl]benzenesulfonamide; CASRN 64902-72-3) was included in the rule and was added to the TRI list effective January 1, 1995.

In the January 12, 1994 proposed rule, USEPA stated that “there is sufficient evidence for listing chlorsulfuron on EPCRA Section 313 pursuant to EPCRA Section 313(d)(2)(B) based on the available developmental and reproductive toxicity data for this chemical.” (USEPA, 1994a) EPA noted in the proposed rule that in a rabbit developmental study an increased incidence of fetal resorptions was observed at the lowest observed effect level (LOEL) of 75 mg/kg/day and that the no observed effect level (NOEL) was 25 mg/kg/day. Also noted in the proposed rule was that in a 3-generation rat reproduction study a decrease in the fertility index was observed at 125 mg/kg/day (LOEL) and that the NOEL was 25 mg/kg/day (USEPA, 1994a).

The toxicity data cited for the above effects in the listing were: 1) a 1980 developmental toxicity study in rabbits (Hoberman et al., 1980) and 2) a 1981 3-generation reproduction study in rats (Wood et al., 1981). These studies have been superseded by newer studies conducted according to USEPA-Guidelines: a 1991 developmental toxicity study in rabbits (Alvarez, 1991) and a 2005 2-generation reproductive toxicity study in rats (Mylchreest, 2005). In addition, a new developmental toxicity study was conducted in rats (Alvarez, 1991b). The adverse effects identified in the original 1980 and 1981 studies that led to the classification of chlorsulfuron under the TRI, did not occur (i.e., were not replicated) in the guideline studies.

In 2002, the Health Effects Division (HED) of the Office of Pesticide Programs (OPP) of the USEPA concluded (USEPA, 2002a) that: “The data provided no indication of increased susceptibility [qualitative and quantitative] following in utero exposure to chlorsulfuron in either the rat or rabbit developmental toxicity study,” regarding the data from the newer guideline studies (Alvarez, 1991, and 1991b). Furthermore, the evaluation of the guideline 2-generation rat reproductive toxicity study on chlorsulfuron by the USEPA in 2007 concluded that there were no adverse effects on reproduction, including the fertility index (Mylchreest, 2005; USEPA, 2007).

Therefore, the USEPA conclusions based on the current EPA-Guideline studies, that there were no teratogenic effects or adverse effects on reproduction, support deletion of chlorsulfuron from the TRI list. In the sections below each specific TRI listing criteria element is addressed and the data presented demonstrate that chlorsulfuron fails to meet each criterion.

### **Specific Criteria Elements**

The information and data presented below support the conclusion that chlorsulfuron does not meet any of the following health and environmental effects criteria, referenced in Section 313(d)(2) of EPCRA; consequently chlorsulfuron should be deleted from the TRI list:

- (A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently occurring, releases.
- (B) The chemical is known to cause or can reasonably be anticipated to cause in humans:
  - i. Cancer or teratogenic effects, or
  - ii. Serious or irreversible:
    - I. Reproductive dysfunction,
    - II. Neurological disorders,
    - III. Heritable genetic mutations, or
    - IV. Other chronic health effects.

The data and rationale that support the assertion that chlorsulfuron does not meet these criteria is found below.

### **Rationale for Deletion of Chlorsulfuron**

**Criterion (A): The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently occurring, releases.**

According to the USEPA's July 17, 2002 Toxicity Chapter for Chlorsulfuron (USEPA, 2002a) on chlorsulfuron from the Health Effects Division (HED) of the Office of Pesticide Programs (OPP) of the USEPA, "the acute toxicity data indicate that chlorsulfuron is not acutely toxic via the oral [Toxicity Category IV], dermal [Toxicity Category III], and inhalation [Toxicity Category IV] routes of exposure." This conclusion is based on results from acute oral, dermal, and inhalation studies on rats referenced in Table 2 of the Toxicity Chapter for Chlorsulfuron (USEPA, 2002a, page 7).

USEPA's subsequent August 14, 2002 final rule establishing a pesticide tolerance for chlorsulfuron (USEPA, 2002c) also noted in the exposure assessment section that "no toxicological endpoint attributable to a single exposure was identified in the available toxicology studies." Furthermore, it was found that "no appropriate studies available show any acute dietary effects of concern." Lastly, in the final rule USEPA concluded that "no acute risk is expected." (USEPA, 2002c)

Finally, in OPP's May 20, 2005 *Reregistration Eligibility Decision for Chlorsulfuron* (USEPA, 2005), the Agency concluded that the "human health risk assessment for chlorsulfuron indicates minimal risks." Additionally, USEPA determined that "dietary exposure from ground water or surface water sources of drinking water are also low and not of concern." Likewise, the Agency noted that "there are no concerns about the risk to homeowners or occupational workers who handle chlorsulfuron or are exposed to residues after chlorsulfuron is applied."

Therefore, based on the above-referenced USEPA conclusions, chlorsulfuron is **not** known to cause and **cannot** reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently occurring, releases. As a result, chlorsulfuron does **not** meet criterion (A).

**Criterion (B)(i): The chemical is known to cause or can reasonably be anticipated to cause cancer or teratogenic effects in humans**

Carcinogenicity

According to the USEPA's July 17, 2002 Toxicity Chapter for Chlorsulfuron (USEPA, 2002a) on chlorsulfuron, the Agency concluded that "there is no evidence of carcinogenicity in rats or mice following oral exposure to chlorsulfuron at dose levels considered adequate for the assessment of carcinogenic potential." Likewise, upon development of a pesticide tolerance in 2002, USEPA classified chlorsulfuron as having "no evidence of carcinogenicity." (USEPA, 2002c)

Teratogenicity

As previously discussed, chlorsulfuron was added to the TRI list of reportable toxic chemicals with an effective date of January 1, 1995. This classification and listing was the result of two studies, a 1980 teratology study in rabbits (Hoberman et al., 1980) and a 1981 3-generation reproductive toxicity study in rats (Wood et al., 1981). These studies have been superseded by USEPA-Guideline studies; a 1991 teratology studies in rabbits (Alvarez, 1991) and a 2005 2-generation reproductive toxicity study in rats (Mylchreest, 2005). The adverse effects identified in the original 1980 and 1981 studies that led to the classification of chlorsulfuron under the TRI, were not replicated in the two replacement studies. The teratology studies are discussed in this section below, while the reproductive studies are discussed under the next criterion.

In 2002, USEPA concluded (USEPA, 2002a) that "there were no teratogenic effects" based on a 1991 teratology study in rats (Alvarez, 1991b) and no adverse effects were observed on the offspring at doses that were toxic to the maternal animal, therefore indicating a lack of teratogenic effects, from the 1991 teratology study in rabbits (Alvarez, 1991).

Rationale for Replacing 1980 Teratology Study in Rabbits with 1991 Teratology Study in Rabbits

USEPA's November 13, 1981 evaluation of the original 1980 teratology study in rabbits stated that "A NOEL of 25 mg/kg body weight was established for fetotoxicity based on an increased incidence of resorptions and lower fetal viability at 75 mg/kg body weight." (USEPA, 1981) This conclusion was repeated in the 1983 chlorsulfuron summary for the USEPA's TRI program (a summary that led to classification of chlorsulfuron under TRI). A new, FIFRA-Guideline developmental toxicity study in rabbits was conducted by DuPont and submitted in 1991 (Alvarez, 1991). The USEPA evaluation of this study, on May 2, 2002, reported that there were no effects of chlorsulfuron on resorptions. The original, 1980 rabbit teratology study (Hoberman et al., 1980) was not further assessed by the USEPA, including during the Agency's development of their 2005 Reregistration Eligibility Decision (RED) document on chlorsulfuron (USEPA, 2005).

Last year, as part of ongoing efforts to delist chlorsulfuron from California Proposition 65, DuPont submitted a Supplement to the original 1980 teratology study in rabbits to California's Office of Environmental Health Hazard Assessment (OEHHA) (Hoberman et al., 1980, Supplement 1, Revision 1, 2011). In the Supplement to the 1980 rabbit study, the data for fetal resorptions from the original study were reviewed, and a clarified interpretation of these data is provided in the supplemental report. The fact that in the 1991 guideline developmental toxicity study in rabbits (Alvarez, 1991) the resorption incidence in treated rabbits was similar to background levels, lacked dose dependency, and did not reproduce the results from the earlier study even at doses of up to 1000 mg/kg/day (a dose more than 10-fold higher than the highest dose in the original 1980 rabbit study) warrants reconsideration of the findings from the 1980 study in which there was no other evidence of developmental toxicity reported.

In summary, the data discussed above and the associated USEPA conclusions support the determination that chlorsulfuron is **not** known to cause and **cannot** reasonably be anticipated to cause cancer or teratogenic effects in humans. As a result, chlorsulfuron does **not** meet criterion (B)(i).

**Criterion (B)(ii)(I): The chemical is known to cause or can reasonably be anticipated to cause serious or irreversible reproductive dysfunction in humans**

As previously mentioned, chlorsulfuron was added to the TRI list of reportable toxic chemicals based on the results of two studies, a 1980 teratology study in rabbits (Hoberman et al., 1980) and a 1981 3-generation reproductive toxicity study in rats (Wood et al., 1981). Again, both of these studies have been superseded by newer USEPA-Guideline studies; a 1991 teratology study in rabbits (Alvarez, 1991) and a 2005 2-generation reproductive toxicity study in rats (Mylchreest, 2005). The adverse effects identified in the original 1980 and 1981 studies, that led to the classification of chlorsulfuron under the TRI were not replicated in the two replacement studies.

Rationale for Replacing the 1981 3-Generation Reproductive Toxicity Study with the 2005 2-Generation Reproductive Toxicity Study

The USEPA's November 10, 1982 evaluation (USEPA, 1982) of the original 1981 3-generation reproductive toxicity study (Wood et al., 1981) reported "A NOEL of 500 ppm based on decreased fertility indices ..." in the third generation, a conclusion based on the statements of the study author at that time. This conclusion was repeated in 1983 in the summary of chlorsulfuron toxicity for the USEPA's TRI program. Subsequently, a new, FIFRA-Guideline 2-generation reproductive toxicity study was conducted in 2005 by DuPont (Mylchreest, 2005). The evaluation of the study by the USEPA in 2007 concluded that there were no adverse effects on reproduction, including the fertility index (USEPA, 2007).

Earlier this year, DuPont, as part of their ongoing efforts to delist chlorsulfuron from California Proposition 65, submitted a Supplement to the original 1981 reproductive toxicity study (Wood et al., 1981, Supplement 3, Revision 2, 2012) to California's OEHHA. The Supplement illustrates that the original conclusion of the study author regarding the fertility index was made in the absence of a statistical analysis and was in error. The Supplemental evaluation supports the conclusion that the NOEL for fertility effects from dietary exposure to chlorsulfuron should be the highest dose tested, 2500 ppm, and not the 500 ppm exposure originally identified by the study author. The evaluations in the current supplement include:

- 1) Comparison to fertility index data from the subsequent 2005 multi-generation reproductive toxicity study.
- 2) Comparison to historical control fertility data from the laboratory, including context to the rat strain variability information from the vendor around that time.
- 3) Statistical analyses of the fertility index data according to USEPA procedures and current standard practice.
- 4) Presentation of the male fertility data not shown previously.

The fertility indices of all the control and treatment groups on study ranged from 79 to 100%, all well within the historical control range of 60 to 100%. No effects on fertility were evident in the subsequent 2005 multi-generation reproductive toxicity study which tested dietary concentrations of up to 7500 ppm, a dose that is three times higher than the highest dose of the 1981 study. Finally, statistical analyses of the Generation 3A and 3B litter data show that there is no significant treatment-related effect in any dose group in that generation. In this regard, both the Cochran-Armitage test and a chi-square analysis showed that there were no significant decreases in mating success in any treatment group, both by trend and pair-wise assessments (Wood et al., 1981, Supplement 3, Revision 2, 2012).

The original 1981 study (Wood et al., 1981) followed an old and rarely used combined chronic toxicity study protocol that incorporated a 3-generation reproductive toxicity study. The original study director, without the benefit or use of statistical methods, came to the conclusion that there was decreased fertility in the third generation of the test animal group treated with the highest doses of chlorsulfuron. It was this conclusion by the original study director that ultimately led to the statement in the USEPA's "OneLiner" database (a paraphrase of the Study Director's statement) that resulted in the 1994 TRI listing. The USEPA's Toxicity Chapter for Chlorsulfuron (USEPA, 2002a, page 14) concluded that the original reproductive toxicity study was an "unacceptable/non-guideline" study, and was considered a "data gap" by the Agency. The Toxicity Chapter detailed several reasons for their conclusion and required that a new reproductive toxicity study be generated (USEPA, 2002a, page 6). A NOAEL of 100 ppm was established for the old study by the USEPA based on decreased female fertility (USEPA, 2002a, page 14), although this was an inadvertent error on USEPA's part – the NOAEL for this study had been established in the original USEPA DER as 500 ppm.

Furthermore, a three-generation reproduction study protocol is not recommended as a routine testing method by the USEPA, the U.S. Food and Drug Administration (FDA), or by European countries. Three-generation reproduction studies have also not been recommended as a part of harmonized guidelines developed by either the Organization for Economic Cooperation and Development or the International Conference on Harmonisation. In fact, starting in the early 1980s, the USEPA concluded that the addition of a 3<sup>rd</sup> generation added no significant understanding to the potential effects of compounds on reproduction or fertility. This has been the position of the Agency since that time. The current USEPA Guidelines for Reproductive Toxicity Risk Assessment were published in 1996 (USEPA, 1996). The 1996 Guidelines describe the 1987 workshop that considered the relative merits of different protocols for reproductive toxicity studies. These current Guidelines do not suggest that a study of 3-generations is either necessary or appropriate for evaluations of the potential reproductive toxicity of a compound.

As such, the 1981 study has been replaced by a state-of-the-art 2005 2-generation rat reproduction study (Mylchreest, 2005), as required by the USEPA. We expect that EPA OPP will no longer use the data generated from the 1981 "unacceptable/non-Guideline" 3-generation reproduction toxicity study (Wood, et al., 1981) in their assessments of chlorsulfuron now that the state of the art reproductive toxicity study (Mylchreest, 2005) has been completed and found to be acceptable by the USEPA.

Therefore, for the reasons stated above, it is apparent that the 1981 study (Wood et al., 1981) in fact indicated that there were no adverse effects on fertility by chlorsulfuron in any generation, consistent with the results of the 2005 multi-generation reproductive toxicity study (Mylchreest, 2005).

In summary, the data discussed above and the associated USEPA conclusions support the determination that chlorsulfuron is **not** known to cause and **cannot** reasonably be anticipated

to cause serious or irreversible reproductive dysfunction in humans. As a result, chlorsulfuron does **not** meet criterion (B)(ii)(I).

**Criterion (B)(ii)(II): The chemical is known to cause or can reasonably be anticipated to cause serious or irreversible neurological disorders in humans**

According to the USEPA's July 17, 2002 Toxicity Chapter for Chlorsulfuron (USEPA, 2002a), the Agency concluded that "there is no evidence of neurotoxicity in any study on chlorsulfuron." The USEPA Hazard Identification Assessment Review Committee (HIARC) reviewed chlorsulfuron toxicity and determined that no additional testing for neurotoxicity was necessary to support chlorsulfuron registration and use (USEPA, 2002a).

Therefore, these USEPA conclusions support the determination that chlorsulfuron is **not** known to cause and **cannot** reasonably be anticipated to cause serious or irreversible neurological disorders in humans. As a result, chlorsulfuron does **not** meet criterion (B)(ii)(II).

**Criterion (B)(ii)(III): The chemical is known to cause or can reasonably be anticipated to cause serious or irreversible heritable genetic mutations in humans**

According to the USEPA's July 17, 2002 Toxicity Chapter for Chlorsulfuron (USEPA, 2002a) on chlorsulfuron, the Agency concluded that "there is no concern for mutagenicity." This conclusion is based on the fact that chlorsulfuron was negative for mutagenicity in a bacterial gene mutation (Ames) assay, negative in the mammalian cell (HGPRT) gene mutation assay, negative in the CHO chromosomal aberrations assay, negative in the dominant lethal assay, and negative in the unscheduled DNA synthesis (UDS) assay in rat hepatocytes (USEPA, 2002a).

In summary, these USEPA conclusions support the determination that chlorsulfuron is **not** known to cause and **cannot** reasonably be anticipated to cause serious or irreversible heritable genetic mutations in humans. As a result, chlorsulfuron does **not** meet criterion (B)(ii)(III).

**Criteria (B)(ii)(IV): The chemical is known to cause or can reasonably be anticipated to cause other serious or irreversible chronic health effects in humans**

Effects of chronic exposure to chlorsulfuron were generally non-specific effects. USEPA reported that no target organ was identified following chronic exposure in either the rat or the mouse study (USEPA, 2002a). Decreased body weight and or body weight gains were the primary effects in the rat, mouse and dog studies. There is no indication that chronic exposure would cause serious or irreversible chronic health effects in humans.

Therefore, these USEPA conclusions support the determination that chlorsulfuron is **not** known to cause and **cannot** reasonably be anticipated to cause other serious or irreversible chronic health effects in humans. As a result, chlorsulfuron does **not** meet criterion (B)(ii)(IV).



## **Conclusion**

Based on the clear USEPA OPP findings presented above resulting from numerous accepted toxicity studies on chlorsulfuron, the conclusion that none of the listing criteria are met warrants the deletion of chlorsulfuron from the TRI list of reportable toxic chemicals.

We truly appreciate your consideration of this petition to delete chlorsulfuron from the TRI list of reportable toxic chemicals. DuPont looks forward to your response and would welcome the opportunity to meet with you to discuss the information contained in this petition. Please contact Richard J. Ambrose, DuPont Crop Protection US Registration Manager at 302-366-5185, or by e-mail at [richard.j.ambrose@usa.dupont.com](mailto:richard.j.ambrose@usa.dupont.com) if you have any questions, would like to set up a meeting, or need further information.

Sincerely,



## Enclosures

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Original Study Date: October 8, 1981. Supplement 3, Revision 2 author: SM Munley.  
Supplement 3, Revision 2 date: February 1, 2012.